JUL 1 7 2000

K001268

510(k) Summary of Safety and Effectiveness

Date:

April 19, 2000

Submitter:

GE Marquette Medical Systems, Inc.
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person:

David Wahlig
Sr. Regulatory Affairs Specialist
GE Marquette Medical Systems, Inc.
Phone: (414) 362-2090
Fax: (414) 371-3736

Device: Trade Name:

GE Marquette Prism Information Server (MPIS) Applications

Common/Usual Name:

Computer, Information network server

Classification Names:

System, Network and Communication, Physiological - 74MSX
Computers and Software, Medical - 80LNX

Predicate Devices:

K854136 Arrhythmia Review Station

Device Description:

The MPIS applications consist of a computer platform to host these five software components:

- RSVP
- AutoView
- PDT
- HL7 Outbound (non-medical application)
- ICMMS (Non-medical application)

Intended Use:

The Marquette Prism Information Server (MPIS) supports several applications both medical and non-medical that extend the capabilities of patient monitors connected to the UnityMC network. The applications also make data from the monitors available to systems not connected to the UnityMC network through modems and secondary network connections. MPIS can display data from any patient connected to a GE Marquette monitor. The server hardware is not patient connected, nor located near the patient or caregiver.

These medical applications are as follows:

- Remote System for Viewing Patients (RSVP) - The RSVP application is intended to allow patient physiological data to be viewed from remote locations.
- AutoView - The AutoView application is intended to monitor the current alarm status of beds residing on the UnityMC network, and automatically changes the bedside view to display information from alarming patients.
- Patient Data Transfer (PDT) - The Patient Data Transfer application is intended to provide intermediate term storage of patient data. This application allows a patient to be discharged from one monitor and re-admitted at another monitor without loss of accumulated data in the patient database.

The MPIS medical applications are intended for use by a licensed healthcare practitioner. The MPIS Applications are intended for use in hospitals, satellite facilities, clinics, and physician's offices.

Technology:

The MPIS computer platform is a commercially available PC running the Microsoft Windows NT Workstation operating system. The RSVP application requires up to 12 modems. The modems are connected to a port server that is in turn connected to the MPIS platform by way of a secondary network.

Test Summary:

The MPIS platform and its applications comply with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the system:

- Requirements specification review
- Code inspections
- Software and hardware testing
- Safety testing
- Environmental testing
- Final validation

Conclusion:

The results of these measurements demonstrated that the MPIS system and its applications are as safe, as effective, and perform as well as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2000

Mr. David Wahlig
Sr. Regulatory Specialist
GE Marquette Medical Systems
A GE Medical Systems Company
8200 W. Tower Ave.
Milwaukee, WI 53223

Re: K001268
GE Marquette Medical Systems Prism Information Server Applications
Regulatory Class: III (three)
Product Code: 74 MHX
Dated: April 19, 2000
Received: April 20, 2000

Dear Mr. Wahlig:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket

notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

510(k) Number (if known): K001268; 510(k) filed on April 19, 2000

Device Name: GE Marquette Prism Information Server (MPIS) Applications

Indications For Use:

The Marquette Prism Information Server (MPIS) supports several applications both medical and non-medical that extend the capabilities of patient monitors connected to the UnityMC network. The applications also make data from the monitors available to systems not connected to the UnityMC network through modems and secondary network connections. MPIS can display data from any patient connected to a GE Marquette monitor. The server hardware is not patient connected, nor located near the patient or caregiver.

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for Mark N Milhorn

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K001268

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)